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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,656	01/04/2001	Peter Forsell	2333-69	1846
27777	7590	08/15/2003		
AUDLEY A. CIAMPORCERO JR. JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER	
			MCCROSKEY, DAVID J	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 08/15/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/753,656	FORSELL, PETER <i>CW</i>
	<b>Examiner</b>	<b>Art Unit</b>
	David J. McCrosky	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 March 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 99 is/are allowed.
- 6) Claim(s) 1-17, 19, 23, 25, 27-72, 75, 77, 82, 85, 87, 88, 91, 93 and 98 is/are rejected.
- 7) Claim(s) 18, 20-22, 24, 26, 73, 74, 76, 78-81, 83, 84, 86, 89, 90, 92 and 94-97 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

The restriction requirement mailed October 1, 2002 is withdrawn. Claims 1-99 are pending.

***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120. Copendency between the current application and the prior application is required. Applicant's have claimed priority to 09/373,224, which was abandoned on October 6, 2000. There is no copendency since the current application was filed on January 4, 2001.

***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because Applicant has made an improper domestic priority claim.

***Specification***

The disclosure is objected to because of the following informalities: the domestic priority claim in the first sentence of the specification should be removed. Appropriate correction is required.

***Claim Objections***

Claims 9, 30, 56, 68, 72, 76, 82 and 84 are objected to because of the following informalities:

- In line 3 of claim 9, "member" should be replaced with --device-- to properly refer to its antecedent;
- In line 1 of claims 30 and 56, "is" should be deleted;
- One of the two periods in claim 68 should be removed;
- Claims 72, 76 and 82 should end with a period; and
- In line 1 of claim 84, "practicedto" should read --practiced to--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-42 and 58-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what action is performed on the hydraulic fluid to contract the cavity.

See "and hydraulic fluid ..." in lines 5 and 6 of claims 33 and 58.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 23, 25, 27-31, 43-45, 50-57, 67-69, 71, 91, 93 and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller. Miller discloses an apparatus and method for operation about or within a constrictable passageway. An exemplary use is for an artificial esophagus. See col. 3, ll. 54-57 and col. 12, ll. 49-55. An implanted adjustment device (106, 107) changes the size of an implanted adjustable restriction device (100). An implanted sensor monitors internal body conditions and the adjustment device is adjusted using a microprocessor controlled device. See col. 5, l. 58 to col. 6, l. 3 and col. 6, ll. 31-42. The implanted control device (112) communicates with an external control unit/wireless remote control (1310). See col. 6, ll. 4-22. The control device (112) contains a clock mechanism, which is used to activate the adjustment device (106) at different times of the day. See col. 5, ll. 45-57. Miller further discloses various sources of deriving electric energy including power transmitted transcutaneously and batteries. See col. 6, ll. 55-65. Examiner considers surgically implanting the adjustable restriction device (100) an inherent feature in the disclosed method. In addition, Examiner considers an accumulator as an inherent feature of a transcutaneous energizing system.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 72, 75, 77, 82, 85 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller as applied to claims 1 and 71 above. Miller discloses monitoring blood pressure and adjusting the applied pressure in proportion to the blood pressure (col. 6, ll. 31-33), but does not teach adjusting in proportion to pressure in the stomach or esophagus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a pressure sensor to monitor the stomach or esophagus since Miller discloses an artificial esophagus embodiment and it was known in the art that pressure in the esophagus or stomach must be monitored when using an artificial esophagus.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller as applied to claims 1, 29 and 30 above. Miller discloses an apparatus as recited for claims 1, 29 and 30. While teaching a mechanism for powering the adjustment device, Miller does not disclose powering the sensor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to power the sensor from wireless energy since it was known in the art that various biomedical devices can be powered transcutaneously.

Claims 46, 48, 49 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller as applied to claims 1, 45, 50 and 69 above. Miller discloses an apparatus as recited for claims 1, 45, 50 and 69. Miller does not teach a capacitor as an accumulator. It would have been obvious to one having ordinary skill in the art at

the time the invention was made to use a capacitor as an accumulator since it was known in the art that a capacitor stores an electrical charge.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller as applied to claim 1 above. Miller discloses an apparatus as recited for claim 1. While teaching a mechanism for powering the adjustment device, Miller does not disclose a battery for powering the sensor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to power the sensor using a battery since it was known in the art that various biomedical devices can be powered using an implantable battery.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 9-17, 19, 43, 71, 82, 88, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 69-75 of U.S. Patent No. 6,475,136 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an

adjustable restriction device, an adjustment device, a sensor and control unit are claimed. The adjustment device is adjusted according to signals from the sensor. An external control unit and a horizontal sensor are also claimed.

Claims 1, 2, 29-32, 43-49, 71, 82, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 40, 41, 44-47, 58, 74-76 and 81-88 of U.S. Patent No. 6,470,892 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because Forsell claims an adjustable restriction device, an adjustment device, a sensor and energy transmission means.

Claims 1-8, 29-32, 43-49, 71, 82, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 36-39, 62-73, 129 and 137-139 of U.S. Patent No. 6,450,946 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

Claims 1-5, 8, 23, 29-32, 43-50, 55-57, 67-71, 82, 91, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-12, 14, 48-54, 58, 59, 95-100 of U.S. Patent No. 6,450,173 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

Claims 1-4, 8, 23, 29, 30, 43-50, 55, 56, 67-72, 82, 91, 93 and 98 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10, 12-16, 22, 42-47, 72-77, 86 and 87 of copending Application No. 10/253,608. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 8, 23, 29-32, 43-50, 55-57, 67-72, 82, 91, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11, 12, 38-49, 63-69 and 93-96 of U.S. Patent No. 6,453,907 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

Claims 1-5, 8, 29-33, 43-49, 71, 72, 82, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 9-17, 48-53, 56-65 and 95-100 of U.S. Patent No. 6,454,699 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

Claims 1-5, 8, 29-33, 43-49, 71, 82, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 20, 37-47 and 62-70 of U.S. Patent No. 6,454,700 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

Claims 1-5, 7, 8, 29-33, 43-49, 71, 82, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11, 22, 38-47 and 64-71 of U.S. Patent No. 6,454,701 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

Claims 1-5, 7, 8, 29-33, 43-49, 71, 82, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12, 47-50, 63-69, 77, 78, 85-90, 101, 103, 149-156, 161, 162 and 169 of U.S. Patent No. 6,461,293 to Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

Claims 1-5, 7, 8, 29-33, 43-49, 71, 82, 93 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 12, 15, 16, 37-41, 77-83, 91-93 and 99 of U.S. Patent No. 6,463,935 to

Forsell. Although the conflicting claims are not identical, they are not patentably distinct from each other because an adjustable restriction device, an adjustment device (operation device), a sensor and control unit are claimed. An external control unit is also claimed.

***Allowable Subject Matter***

Claim 99 is allowed.

The following is an examiner's statement of reasons for allowance: the prior art does not disclose a method of implanting an adjustable restriction device, adjustment device and sensor in a laparoscopic surgical procedure.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 18, 20-22, 24, 26, 73, 74, 76, 78-81, 83, 84, 86, 89, 90, 92 and 94-97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

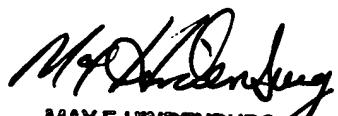
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM  
August 2, 2003



MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
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